K023573

NOV 21 2002

510(K) SUMMARY

WizAir DVT™

510(k) Number K_____

Applicant's Name:

Medical Compression Systems (DBN) Ltd.
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Or-Akiva 30600, Israel
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mcs@mcsmed.com

Contact Person:

Arava Hacohen
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131

Trade Name:

WizAir DVT™

Classification Name:

Compressible Limb Sleeve

Classification:

Class II; Product Code JOW; Regulation No. 870.5800.

Device Description:

The *WizAir DVT™* is a prescriptive, pneumatic compression device designed to apply sequential compression to the lower limb. The control unit of the *WizAir DVT™* is light and compact, thus making it a portable ambulant system. The *WizAir DVT™* provides the user with an option of battery operation in addition to the operation from the mains option. The *WizAir DVT™* is easy to use and provides the user with several treatment options: compression of the foot – single or double (either regular foot or foot booster), compression of the calf – single or double, compression of the Thigh – single or double, and combined compression of any combination of two cuffs.
The foot compression program is sequential intermittent pressure pulse application to a single celled foot cuff. The calf and thigh compression program is a sequential intermittent gradient application of a pressure to a three-celled calf cuff.

Indications:

The *WizAir DVT™* is a prescriptive device that induces Continuous Enhanced Circulation Therapy of the lower limbs.

The *WizAir DVT™* is intended for use in:

- Preventing Deep Vein Thrombosis (DVT).
- Enhancing blood circulation.
- Diminishing post-operative pain and swelling.
- Reducing wound-healing time.
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers.
- Treatment of chronic venous insufficiency.
- Reducing edema.

Contraindications:

The *WizAir™* system should not be used in the following cases: fresh pre-existing DVT, pulmonary embolism, leg gangrene, recent skin graft, acute thrombophlebitis and in medical situations where increased venous and lymphatic return is undesirable

Statement Substantial Equivalence:

The modified ***WizAir DVT™*** System is substantially equivalent in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc., to the commercially available ***WizAir DVT™***. The modified ***WizAir DVT™*** System includes an additional cuff – the Foot Booster cuff for faster inflation of the cell.

The pressure profile of the new cuff is similar to that of the A-V Impulse System. Moreover, the additional cuff and software modification were verified through bench testing and validated through clinical analysis that was performed on healthy volunteers.

Testing results showed that the Foot Booster performs according to its specifications in safe and effective manner.

Performance Data:

A series of safety and performance testing including bench testing and clinical comparison between the Foot Booster cuff of the ***WizAir DVT™*** and its predicate device demonstrated that the modified ***WizAir DVT™*** System is substantially equivalent to its predicate devices without raising new safety and/or effectiveness issues

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

Medical Compression Systems (D.B.N.) Ltd.
c/o Mr. Arava Hacohen
Project Manager
Push-med Ltd.
117 Ahuzah St.
Ra'ananna 43373
ISRAEL

Re: K023573
Trade Name: WizAir DVT™
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II (two)
Product Code: JOW
Dated: October 21, 2002
Received: October 24, 2002

Dear Mr. Hacohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: *WizAir DVT™*

Indications for Use:

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The *WizAir DVT™* is intended for use in:

- Preventing Deep Vein Thrombosis (DVT).
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- Treatment of chronic venous insufficiency.
- Reducing edema.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Division of C... Respiratory Devices
510(k) Nu... K023573

510(k) Number _____

Prescription Use _____ OR Over the Counter Use_____
(Per 21 CFR 801.109)